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			WANG, CHANG YU	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Application No. Applicant(s) 10/590,526 KODAMA ET AL Office Action Summary Examiner Art Unit Chang-Yu Wang 1649 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 30 January 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-7 and 12-20 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

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DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

- Applicant's amendment filed 1/30/09 is acknowledged. Claims 1-3 are amended.
 Claims 12-20 are newly added. Claims 1-11 and newly added claims 12-20 are pending in this application. Claims 8-11 are withdrawn without traverse (the response filed on 1/2/08) from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.
- 2 Claims 1-7 and 12-20 are under examination in this office action
- Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.
- Applicant's arguments filed on 1/30/09 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Withdrawn

The objection to claims 1 and 4-7 is withdrawn in response to Applicant's amendment to the claims.

The rejection of claims 1-3 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in response to Applicant's amendment to the claims.

Claim Rejections/Objections Maintained

In view of the amendment filed on 1/30/09, the following rejections are maintained.

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Claim Rejections - 35 USC § 112

6. The following is a guotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 12-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diagnosis of coronary artery condition (CA), unstable angina (UAP) and myocardial infarction (AMI) by measuring an increased level of PTX3 using an anti-PTX antibody in patients with the above conditions as compared to defined controls, does not reasonably provide enablement for a method for assessing the extent of vascular injury or determining an undefined heart disease or cerebrovascular disease by determining the level of PTX3 using an antibody recognizing the full length PTX3 or a peptide fragment thereof and wherein the extent of vascular injury is rated by undefined histological parameters as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The rejection is maintained for the reasons made of record.

Claims 1-7 and 12-20 as amended are drawn to a method of assessing the extent of vascular injury by immunoassay the level of PTX3 by an anti-PTX3 antibody in a test sample from a subject compared to a control sample wherein the extent of vascular injury is rated by at least one of the following histological parameters (a) lipid core size, (b) thickness of fibrous cap, (c) strength of shear stress and (d) extent of inflammatory infiltration, wherein the test sample is blood, serum or plasma and wherein

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the extent of vascular injury represents the severity of heart disease or cerebrovascular disease. Claims 16-20 are directed to detecting patients who have already diagnosed as having no cardiovascular disease, myocardial infarction, or cerebrovascular disease, or who have been diagnosed as having diabetes or being overweight or smoking but no cardiovascular or cerebrovascular disease.

On p. 8 of the response, Applicant argues that the rejection has been overcome because claim 1 has been amended and Immunoassays useful for measuring PTX3 levels were known in the art. Applicant further cites Peri et al. (Circulation. 2000. 102:636-641) and Latini et al. (US2004/0137544) in support of the arguments. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, the specification does not teach what levels of PTX3 are correlated to what degrees of the recited histological parameters in patients who suffer from all forms of vascular injury as recited in amended claim 1. The instant specification only shows that the level of PTX3 in blood of patients suffering from CA, UAP and AMI is higher and the pathological conditions of these patients are severe as compared to patients without CA, UAP and AMI.

There is no guidance or correlation between the levels of PTX3 and the extent of different histological parameters, and thereby it is unknown what specific levels of PTX3 can be used as an indicator of the extent of different forms of vascular injury. There is no guidance of which level of PTX3 is considered as normal and which level would be the severity of heart disease or cerebrovascular disease.

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In addition, the specification fails to define what criteria would be considered as a control and thus can be used in the claimed method.

Furthermore, claim 7 recites peptide fragment thereof. However, the specification fails to teach which specific fragments can be detected by the claimed anti-PTX3 antibody. It is known in the art that each PTX3 peptide or polypeptide forms specific epitopes for an anti-PTX3 to recognize. However, the specification does not teach what specific common structures/amino acid sequences are required for the claimed fragments to be recognized by the claimed anti-PTX3 antibodies.

Moreover, claims 16-20 are directed to patients who have already diagnosed as having no cardiovascular disease, myocardial infarction, or cerebrovascular disease, or who has been diagnosed as having diabetes or being overweight or smoking but no cardiovascular or cerebrovascular disease. It is unclear what Applicant intended to include in the claims. The instant methods are directed to assessing the extent of a vascular disorder based on the relationship between the histological condition and the expression level of PTX3. The specification fails to teach the specific level of PTX3 as an indicator of the extent of vascular injury. The specification also fails to teach the expression levels of PTX3 in patients who have been diagnosed with no cardiovascular disease, myocardial infarction, or cerebrovascular disease, or who have been diagnosed as having diabetes or being overweight or smoking but no cardiovascular or cerebrovascular disease. Applicant cannot use an unknown parameter (an unknown level of PTX3) to determine another unknown outcome. Note that

[&]quot;The 'predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is

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predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971) See MPEP S 2164.03

 Claims 1-7 and 12-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The rejection is maintained for the reasons made of record.

On p. 8-9 of the response, Applicant argues that Applicant is in possession of the method of assessing vascular injury other than CA, UAP and MCI. Applicant argues that the specification discloses different conditions on p. 8, line 15 and p. 8-9. Applicant argues that measuring PTX3 levels are described on p. 6, lines 3-5. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, the specification fails to teach the correlation between the diseases of CA, UAP and MCI, and other undefined vascular diseases. In addition, the specification fails to describe what a defined control sample is. There is no specific correlation between the recited histological parameters and the levels of PTX3. Thus, a skilled artisan cannot envision the functional correlation between the claimed diseases and the claimed invention. In addition, the specification fails to demonstrate that Applicant is in possession of the claimed genus of fragments to be recognized by the claimed anti-PTX3. The specification fails to describe the common structures and sequences that are required for the claimed fragments. Thus, the specification fails to reasonably

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demonstrate that Applicant is in possession of the claimed method as currently written.

Note that

A definition by function alone "does not suffice" to sufficiently describe a coding sequence because it is only an indication of what the gene does, rather than what it is." Eli Lilly, 119 F.3 at 1568, 43 USPQ2d at 1406. See also Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen Inc. v.Chugal Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)). An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., Univ. of Rochester v. G.D. Searle &Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filted in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 and 12-15 are rejected under 35 U.S.C. 102 (b) as being anticipated by Peri et al. (Circulation. 2000, 102:636-641 as in IDS). The rejection is based on the subject matter that is enabled within the claims as set forth in section of 112-1st paragraph. The rejection is maintained for the reasons made of record.

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Claims 1-7 and 12-15 as amended are drawn to a method of assessing the extent of vascular injury by immunoassay the level of PTX3 by an anti-PTX3 antibody in a test sample from a subject compared to a control sample wherein the extent of vascular injury is rated by at least one of the following histological parameters (a) lipid core size, (b) thickness of fibrous cap, (c) strength of shear stress and (d) extent of inflammatory infiltration, wherein the test sample is blood, serum or plasma and wherein the vascular injury represents the severity of heart disease or cerebrovascular disease.

On p. 9 of the response, Applicant argues that Peri does not teach the use of PTX3 as a marker to assess the extent of vascular injury as determined by the criteria described in amended claim 1 because Peri only teaches a method of using PTX3 as an early indicator of myocardial infarction (MCI). Applicant argues that new claims 16-17 exclude methods using test samples from subject having MCI. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, Peri does teach the claimed method because the active steps within claim 1 are determining immunoassays on the level of PTX3 in a test sample and comparing the level to a control sample, which are disclosed by Peri. Peri teaches that PTX3 plasma concentrations are higher in patients suffering from acute myocardial infarction, which is myocyte irreversible injury in ischemic cardiomyopathy (i.e. a condition of vascular injury as in instant claim 1 and is a heart disease as in instant claim 2) (see p. 637, 1st col-2nd col.). Peri et al. teach detection of PTX3 plasma concentrations via an ELISA method using an anti-PTX3 antibody (see p. 637, 2nd col.-p. 638, 1st col.).

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The limitation of histological parameters recited in claim 1 is in a wherein clause and is to express intended results and thus is not given patentable weight. In addition, the arguments with regard to claims 16-17 are irrelevant because claims 16-17 are not included in this rejection.

9. Claims 1-7 and 12-15 are rejected under 35 U.S.C. 102(a) & (e) as being anticipated by US2004/0137544 (Latini et al., published Jul 15, 2004, priority Oct 31, 2002). The rejection is based on the subject matter that is enabled within the claims as set forth in section of 112-1st paragraph. The rejection is maintained for the reasons made of record.

On p. 9-10 of the response, Applicant argues that Latini does not teach using a marker to assess the extent of vascular injury as determined by the criteria described in claim 1. Applicant argues that Latini does not contemplate obtaining test samples from subjects not having AMI or ictus as in claims 19-20. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, the only active steps within claim 1 are determining immunoassays on the level of PTX3 in a test sample and comparing the level to a control sample. Such active steps are disclosed by Latinin (see p. 1, [0004]-[0009]). Latinin teaches a method of diagnosing patients with myocardial infarction (i.e. heart disease) or cerebral ictus (i.e. cerebrovascular disease) by measuring the plasmatic level of PTX3 via an immunoassay method with an anti-PTX3 antibody (see p. 1, [0004]-[0010]; p. 2,

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example 2). Latinin teaches that an increased level of PTX3 in patients' plasma is an indicator of risk of death or complications for the diseases.

The new limitation of histological parameters recited in amended claim 1 is in a wherein clause. Note that the limitation recited in a method claim within a wherein clause is given patentable weight when the limitation is to express the intended result of a process step. Note that

In Hoffer v. Microsoft Corp., 405 F.3d 1326, 1329, 74 USP02d 1481, 1483 (Fed. Cir. 2005), the Gourt held that when a "whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." Id. However, the court noted (quoting Minton v.Nat'l Ass'n of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USP02d 1614, 1620 (Fed. Cir. 2003)) that a "whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited." Id. < See MPEP § 2111.04.

Further, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., claims 19-20) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

- 10. Claims 1-7 and 12-15 are rejected under 35 U.S.C. 102 (a) as being anticipated by Latini et al. (Circulation 2004, 110:2349-2354, as in IDS). The rejection is based on the subject matter that is enabled within the claims as set forth in section of 112-1st paragraph. The rejection is maintained for the reasons made of record.
- On p. 10 of the response, Applicant argues that Latini's method only involves use of PTX3 as a prognostic marker for disease outcomes in a subject having acute

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coronary syndrome not a marker to assess the extent of vascular injury. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, Latini does teach the claimed method because the active steps in claim 1 are determining immunoassays on the level of PTX3 in a test sample and comparing the level to a control sample. Such active steps are disclosed by Latini. Latini teaches a method of detecting an increased level of PTX3 in acute myocardial infarction, which is a condition of vascular injury, as recited in instant claims (see p. 2349, abstract; p. 2350, 1st col., 3rd-4th paragraphs; p. 2352, 1st col., 1-3rd paragraphs). Latini teaches the use of the increased level of PTX3 as an indicator for detecting acute myocardial infraction. Latini teaches detection of an increased level of PTX3 in blood of patients suffering from heart failure, cardiac ischemia and acute coronary syndrome as compared to controls (see p. 2350, 1st col., 3rd-4th paragraphs). Heart failure, cardiac ischemia and acute coronary syndrome are heart diseases and are a form of vascular injury.

The histological parameters recited in amended claim 1 is in a wherein clause.

Note that the limitation recited in a method claim within a wherein clause is given patentable weight when the limitation is to express the intended result of a process step.

Thus, Latini teaches the claimed method.

Obviousness-Type Double Patenting

^{11.} The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the 'right to exclude' granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 14046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1960).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 12-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 12/092272. The rejection is maintained for the reasons made of record.

On p. 10-11 of the response, Applicant argues that the forgoing amendments and remarks address the remaining rejections and place the instant application in condition for allowance. Applicant argues that based on MPEP 804 (I)(B), the instant provisional rejection can be withdrawn because the pending applicant has not been allowed. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, amended claims are not allowable and the amendment and the remark haven't overcome the remaining rejections. Thus, the ODP rejection is maintained of record until a terminal disclaimer is filed.

New Grounds of Rejection Necessitated by the Amendment

The following rejections are new grounds of rejections necessitated by the amendment filed on 1/30/09.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 16-20 are directed to a method of assessing the extent of vascular injury by immunoassay the level of PTX3 by an anti-PTX3 antibody in a test sample from a subject compared to a control sample wherein the extent of vascular injury is rated by at least one of the following histological parameters (a) lipid core size, (b) thickness of fibrous cap, (c) strength of shear stress and (d) extent of inflammatory infiltration, wherein the test sample is blood, serum or plasma, wherein the extent of vascular injury represents the severity of heart disease or cerebrovascular disease and wherein the test sample is obtained from a subject who has been diagnosed as having no cardiovascular disease, myocardial infarction, or cerebrovascular disease, or who has been diagnosed as having diabetes or being overweight or smoking but no cardiovascular or cerebrovascular disease.

The instant claims now recite limitations of a subject who has been diagnosed as having no cardiovascular disease, myocardial infarction, or cerebrovascular disease, or who has been diagnosed as having diabetes or being overweight or smoking but no cardiovascular or cerebrovascular disease, which were not clearly disclosed in the

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specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

The specification fails to disclose the limitations as recited in instant claims 16-20. Accordingly, in the absence of sufficient recitation of such new limitations, the specification does not provide adequate written description to support the new limitations as recited in instant claims 16-20. Support is not found for these new limitations as disclosed in the original specification and thus the recitations constitute new matter absent evidence for their support. Applicant is required to cancel the new matter in the reply to this office action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

Conclusion

- 13. NO CLAIM IS ALLOWED.
- THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/ Chang-Yu Wang, Ph.D. April 29, 2009

/Christine J Saoud/ Primary Examiner, Art Unit 1647